EXAMINER'S AMENDMENT

1. This action is responsive to the amendments and response filed January 2, 2009. Claims 28-32, 34-38, 40-41, 44, 47, 49, 52, and 54-57 are now allowed, subject to the examiner's amendment set forth below. In accordance with 37 C.F.R. 1.126, allowed claims 28-32, 34-38, 40-41, 44, 47, 49, 52, and 54-57 will be renumbered as claims 1-20, respectively (see MPEP 608.01(j)). Original claim numbering is employed in the instant examiner's amendment.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Laurence Manber on September 25, 2009.

Summary of the interview concluding September 25, 2009

3. On September 21, 2009, the examiner left a telephone message for Donald Lucas and faxed a proposed amendment that would place the application in condition for allowance. Laurence Manber returned the examiner's call, and the application was briefly discussed. The examiner noted that the majority of the proposed amendments were for purposes of further clarify the claims; however, she had proposed deleting reference to "corresponding gene(s)" for reasons set forth in the enablement rejection of record, and particularly because the claimed sequences are disclosed as being intercistronic (such that no "corresponding" gene appears to have been disclosed). The

examiner also noted that some claims had been amended to make clear that they were limited to the single "corresponding" RNA version of the recited SEQ ID NOs; the examiner indicated that these particular RNA molecules were enabled, and that basis for them is provided in, e.g., applicant's disclosure of the RNA version of disclosed sequences (at, e.g., page 7 of the specification). Applicant's representative indicated that he would consult with applicant and contact the examiner again as soon as a reply was received. On September 25, 2009, applicant's representative contacted the examiner and authorized the proposed amendments.

4. **Amend the claims as follows**:

Claim 35

A nucleotide probe consisting of a nucleotide sequence selected from the group consisting of ~~sequence~~ SEQ ID No: 1, the complement of SEQ ID No: 1, the RNA sequence corresponding to SEQ ID NO: 1, and the RNA sequence corresponding to the complement of SEQ ID NO: 1 ~~their corresponding RNA sequences and their corresponding gene(s)~~.

Claim 37

A nucleotide probe consisting of 21 consecutive nucleotides of a region of sequence SEQ ID No: 2 comprising the GAG codon in positions 40 to 42 or the complement of said 21 consecutive nucleotides ~~region~~.

Claim 38

A nucleotide probe consisting of ~~a nucleotide sequence which consists of~~ nucleotides ~~in positions~~ 31 to 51 of SEQ ID No: 2 or the complement thereof ~~of said sequence~~.

Claim 41

A nucleotide probe consisting of a [[the]] nucleotide sequence selected from the group consisting of SEQ ID No: 1, SEQ ID No: 2, the complement of SEQ ID No: 1, the complement of SEQ ID No: 2, the RNA sequence corresponding to SEQ ID NO: 1, the RNA sequence corresponding to the complement of SEQ ID NO: 1, the RNA sequence corresponding to SEQ ID NO: 2, and the RNA sequence corresponding to the complement of SEQ ID NO: 2, ~~their corresponding RNA sequences and their corresponding gene(s)~~ wherein said nucleotide probe is labeled by digoxygenin.

Claim 47

A method of detecting a mycobacteria strain of M. tuberculosis complex in a biological sample comprising the steps of:

(1) contacting the biological sample to a pair of primers 5'GCGCGAGAGCCCGAACTGC3' (SEQ ID No: 4) and 5'GCGCAGCAGAAACGTCAGC3' (SEQ ID No: 5) under conditions to

effect hybridization of the primers to a nucleotide sequence of mycobacteria strains of M. tuberculosis complex;

(2) amplifying said nucleotide sequence with said primers;

(3) contacting said nucleotide sequences amplified from step (2) with a nucleotide probe consisting of a nucleotide sequence selected from the group consisting of SEQ ID No: 1, SEQ ID No: 2, the complement of SEQ ID No: 1, the complement of SEQ ID No: 2, the RNA sequence corresponding to SEQ ID NO: 1, the RNA sequence corresponding to the complement of SEQ ID NO: 1, the RNA sequence corresponding to SEQ ID NO: 2, the RNA sequence corresponding to the complement of SEQ ID NO: 2, nucleotides 31 to 51 of SEQ ID No: 2, and the complement of nucleotides 31 to 51 of SEQ ID No: 2 ~~their corresponding RNA sequences and their corresponding gene(s)~~, or with a nucleotide probe having[[,]] a sequence comprising two successive sequences of SEQ ID No: 1 followed by a sequence of SEQ ID No: 2, under conditions for formation of hybridization complexes between said probe and said nucleotide sequences amplified from step (2); and

(4) detecting the presence or absence of complexes, wherein the presence of complexes is indicative of the [[a]] presence of a mycobacteria strain of *M. tuberculosis* complex.

Claim 49

The method of claim 47 wherein the ~~sequence of the~~ nucleotide probe consists of nucleotides ~~in positions~~ 31 to 51 of SEQ ID No: 2 or the complement of nucleotides 31 to 51 of SEQ ID No: 2.

Claim 55

A method of detection and of differential diagnosis of BCG and the members of M. tuberculosis complex in a biological sample comprising the steps of:

(1) contacting the biological sample to a nucleotide primer pair comprising a pair of primers 5'GCGCGAGAGCCCGAACTGC3' (SEQ ID No: 4) and 5'GCGCAGCAGAAACGTCAGC3' (SEQ ID No: 5)

under conditions to effect hybridization of the primers to ~~said~~ nucleotide sequences of mycobacteria of M. tuberculosis complex;

(2) amplifying said nucleotide sequences with said primers;

(3) contacting the biological sample containing said nucleotide sequences amplified from step (2) with a nucleotide probe having a sequence comprising two successive sequences SEQ ID No: 1[[,]] followed by a sequence SEQ ID No: 2 under condition for formation of hybridization complexes between said probe and said nucleotide sequences amplified from step 2;

(4) detecting any first hybridization complexes present; and

(5) determining if said first hybridization complexes are also capable of forming second hybridization complexes with a nucleotide probe, the sequence of which consists of nucleotides ~~in positions~~ 31 to 51 of SEQ ID No: 2, or the complement of nucleotides 31 to 51 of SEQ ID No: 2 ~~said sequence~~, for detection of sequences of nucleic acids of M. tuberculosis complex other than BCG, the [[a]] presence of said second hybridization complexes being indicative of the [[a]] presence of a M. tuberculosis strain different from BCG and the [[a]] presence of said first hybridization complexes uniquely being indicative of BCG.

5. **The following is an examiner's statement of reasons for allowance**.

With regard to the allowability of claim 32, the claim references deposited plasmids. While applicant's specification provides complete deposit information (see amendment of February 28, 2002) regarding these constructs, applicant has not provided a statement that restriction on availability to the public will be irrevocably removed upon grant of a patent. However, in the present case, the detailed guidance and sequence information provided in the specification, in combination with information and materials readily available to those of skill in the art, would allow one of ordinary skill to prepare each of the claimed plasmids without undue experimentation. Accordingly, a perfected deposit is not required to enable the invention of claim 32 (see MPEP 2404.02).

It is also noted that, as the prosecution history makes clear, language such as "consisting of a nucleotide sequence selected from the group consisting of" (as in exemplary claim 28/renumbered claim 1) as employed in the instant claims requires a nucleic acid consisting of the full length of one of the recited members of the Markush group.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571/272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Diana B. Johannsen/
Primary Examiner, Art Unit 1634